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TOUGH® 3.75 EC  
CFR 40 SECTION 158 DATA REQUIREMENTS  
SUMMARY OF STATUS

0-1 61-1, Identity of Ingredients and 61-2, Statement of Composition:

Please see the original Confidential Statement of Formula (CSF).

0-2 61-3, Discussion of Formation of Impurities:

A discussion of the formation of impurities in the technical was included in the original submission for the Tough® 45 WP product dated 1/23/84. Formulation consists of blending of the ingredients to produce the final product. It is a simple mixing operation and does not result in the production of any new impurities.

0-3 62-3, Analytical Methods:

Analytical methods for the analysis of the Pyridate technical, Tough 45 WP and Tough® 3.75 EC were included in the original submission of 1/23/84, accession number 072353.

Please Note: In response to a letter from Gilmore, July 14, 1987, requesting the status of Section 158.120 Product Chemistry for both Tough® 3.75 EC and Tough® 45 WP the Agency confirmed in their letter of October 1, 1987 that the only comments by the reviewing branches concerned the original Confidential Statement of Formula for Tough® 45 WP and one of the inert ingredients in that formulation. Those concerns have been resolved and it is now assumed by the registrant that all requirements for Product Chemistry are satisfied for both products.

0-4 81-1, Acute Oral LD50 Rat:

A study utilizing Pyridate technical as the test article was submitted 1/17/85. The study, accession number 73280, was reviewed and classified as core guideline on 2/12/86. The resulting LD50's were: Males - 5993 mg/kg; Females - 3544 mg/kg; Both sexes - 4690 mg/kg. On 1/25/85 a study utilizing Tough® 3.75 EC as the test article was submitted. It was reviewed, accession number 73307, and classified as core guideline on 2/12/86. The resulting LD50's were: Males - 1871 mg/kg; Females - 905 mg/kg; Both sexes - 1258 mg/kg.

O-5 81-2, Acute Dermal LD50:

A study for Pyridate technical was submitted on 1/17/85. The study was assigned accession number 73280 reviewed, and classified as core guideline by the Agency on 2/12/86. Results of the study indicated an LD50 dermal of 2000 mg/kg for the test article. On 1/25/85 a study using the formulated product, Tough' 3.75 EC, was submitted. The study was assigned accession number 73307, reviewed, and classified as core guideline on 2/12/86. The LD50 dermal for the test article was determined to be 200 mg/kg.

O-6 81-3, Acute Inhalation LC50:

A study for Pyridate technical was submitted 1/23/84 and assigned accession number 73280. Review of the study indicated additional data was needed, which was submitted by the registrant on 1/17/85. With the additional data the study was classified as core minimum on 2/12/86. An acute inhalation study for Tough' 3.75 EC was submitted on 1/25/85. Accession number 73307 was assigned and the study was reviewed on 2/12/86 and classified as core guideline.

The acute 4 hour inhalation toxicity of Pyridate technical in rats of both sexes, observed over a period of 14 days was estimated to be greater than 4370 mg/cbm of air. Due to technical difficulties the exposure to higher concentrations was not possible.

The LC50 from exposure to Tough' 3.75 EC for 4 hours was observed to be: LC50 = 3492 mg/cbm of air for both sexes over an observation period of 15 days. The LC50 for 22 days observation period was 3282 mg/cbm air for both sexes.

O-7 81-4, Primary Eye Irritation:

The original submission of the study was 1/25/85. The study followed OECD guidelines and was classified as core minimum on 2/12/86, accession number 73307.

O-8 81-5, Primary Dermal Irritation:

The original submission was made on 1/25/85. The study was assigned accession number 73307 and classified as core minimum on 2/12/86.

O-9 81-6, Dermal Sensitization:

A total of 4 dermal sensitization studies have been conducted on Pyridate compounds and formulations: 1) purified Pyridate, 2) Pyridate technical, 3) Tough® 45 WP, and 4) Tough® 3.75 EC. The results of each study indicated that Pyridate and formulations of Pyridate are sensitizers in albino guinea-pigs. The statement "This product may cause sensitization in some individuals" will be added to the label.

O-10 82-1, 90 Day Feeding, Rat:

The original study submitted 1/23/84 was classified as supplemental. The study was re-run and submitted 4/6/87. Upon review the new study was classified as core guideline. MRID number 401057401, with NOEL of 62.5 mg/kg/day and an LEL of 177 mg/kg/day.

O-11 82-1, 90 Day Feeding, Dog:

The original study was submitted to the Agency on 1/23/84. It was reviewed and classified as core supplemental on 3/20/86. Additional data was submitted and reviewed on 8/20/84, but was insufficient to re-classify the study. The study was re-run and submitted to the Agency on 2/27/87. MRID number 40101604 was assigned and the new study was reviewed and classified as core guideline on 7/14/87.

O-12 83-1, Chronic Feeding, Rat:

The original study, submitted 1/23/84, accession number 72342, was reviewed and classified as core supplemental by the agency on 7/8/86. The deficiencies were addressed in a supplemental data package which was submitted to the Agency on 12/23/87. The supplemental data addresses all of the deficiencies listed in the review of 6/29/86 and is believed by the registrant to be sufficient to re-classify the study.

O-13 83-1, Chronic Feeding, Dog:

The original study, submitted 1/23/84, accession number 72344, was reviewed by the Agency and classified as invalid on 4/15/86. After careful review the registrant agrees with the Agency's findings. A new 12-month dog study was initiated on 8/1/87 and is now running at Hazleton Laboratory, Vienna, Virginia. The final report is due 3/87. An interim report can be made available to the Agency, if desired.

0-14 83-2, Oncogenicity, Rat:

The original study was submitted to the Agency on 1/23/84, and assigned accession number 72343. The oncogenicity and chronic feeding, rat, was a combined study. Please see comments on the chronic feeding rat study as they relate to both.

0-15 83-2, Oncogenicity, Mouse:

The original study was submitted 1/23/84. It was assigned accession number 72346, reviewed, and classified as supplemental by the Agency on 10/5/86. It was indicated that the study could be upgraded to core-minimum if listed deficiencies were resolved. TNO Laboratories, the original producer of the study, is currently preparing supplemental data to address the indicated deficiencies. The expected completion date is 2/88.

0-16 83-3 Teratogenicity, Rat:

The original study, submitted 1/23/84 was reviewed by the Agency and classified as core supplemental on 5/18/84. Additional data was submitted but was not sufficient to re-classify to core-minimum. The study was re-run and submitted 5/86 for review. It was assigned accession number 262546 and classified as core-guideline in the Agency's review of 8/20/86.

0-17 83-3, Teratogenicity, Rabbit:

The original study was submitted on 1/23/84. It was assigned accession number 72348, review and classified as core-supplemental by the Agency on 12/5/86. A second study, accession no 259948, was submitted 10/14/85. It was reviewed 6/9/86 and also classified as core-supplemental. A third study, started fall 1987, was submitted to the Agency on 12/14/87. This study demonstrates maternal toxicity and has a NOEL of 150 mg/kg/day and an LEL of 300 mg/kg/day. There were no observed compound related teratogenic effects.

0-18 83-4, Multigeneration reproduction, Rat:

The original study was submitted to the Agency on 1/23/84. It was reviewed, assigned accession number 72347 and classified as core supplemental on 12/5/86. The Agency indicated in the review that the study could be up graded to core-minimum if deficiencies were corrected. The originator of the study, TNO, Netherlands, is currently preparing a response. Supplemental information will be available 2/88.

0-19 84-2, Battery of Mutagenicity Tests:

Gilmore submitted a battery of 6 mutagenicity tests on 1/23/84 to satisfy the mutagenicity testing requirement. In their review of 5/14/86, accession number 72348, the Agency found all but one of the studies unacceptable and recommended repeating the others. Gilmore has conducted additional studies and has satisfied the requirements of Gene Mutation, and Structural Chromosomal Aberration groups. A new Bacillus subtilis study intended for the Other Genotoxic Effects group was rejected for failure to show toxicity. This was caused by the limited solubility of the compound. A new study is currently underway at Hazleton Laboratories, Netherlands, using a modified protocol with suspension technique. This study will be completed December 1987 with the final report submitted 1/88. The study will meet EPA requirements.

It should be pointed out that even though some of the mutagenicity tests did not meet EPA's strict guidelines, none demonstrated any evidence of a mutagenic effect. This fact was commented upon by Dr. David Brusick, Hazleton Laboratories, a recognized authority on mutagenic effects, in a submission by Gilmore to the Agency on 9/19/86.

0-20 85-1, General Metabolism:

Of the eleven original studies submitted on 1/23/84, six were classified as core supplementary and one as core-minimum in the Agency's review of 12/18/86, accession number 72349. Rather than try to correct the deficiencies of the individual studies it was decided to re-run the entire metabolism study. The study is currently in progress at Inveresk Laboratories, Scotland. A preliminary report will be available 2/88, with final report available in late summer 1988.

0-21 71-1, Avian Oral LD50, Bobwhite:

The original study was submitted to the Agency on 1/23/84. It was assigned accession number 72350 and reviewed on 9/30/85. The study was found unacceptable. A new study was commissioned and the final report received 5/2/86. It was submitted to the Agency on 10/9/86. Additional copies of the study were requested by the Agency on 10/1/87. Acknowledgement of the additional copies was made on 10/21/87 and MRID number 40373201 was assigned. An expedited review has been promised by the Agency. It should be noted that the results of the second study, LD50 = 1023 - 1577 mg/kg (95% confidence limits) were well within the results of the original study of LD50 = 1505 mg/kg (1204 - 1803 mg/kg, 95% confidence limits).

0-22 71-2, Avian Dietary LC50, Mallard Duck and Bobwhite:

The following two studies were submitted to the Agency on 1/23/84:

1. A DIETARY LC50 STUDY IN THE BOBWHITE WITH PYRIDATE. Project No 190-101. J. Beavers, Wildlife International, 1984. The dietary LC50 value of Pyridate in the bobwhite was determined by inspection to be greater than 5000 ppm.

2. A DIETARY LC50 STUDY IN THE MALLARD WITH PYRIDATE. Project 190-102. J. Beavers, Wildlife International, 1984. The dietary LC50 value of Pyridate in the Mallard was determined by inspection to be greater than 5000 ppm.

The studies were assigned accession number 72350, reviewed on September 30, 1985, and accepted as fulfilling the requirement for Avian LD50 in wild waterfowl and upland fowl species.

0-23 71-4, Avian Reproduction, Mallard Duck and Bobwhite:

The final reports for both studies have been received and are a part of this registration submission.

The results show that for the bobwhite there were no treatment related effects upon adult birds exposed to dietary concentrations of 256, 640, or 1600 parts per million(ppm) Pyridate technical. No treatment related effects upon reproductive performance were noted. The no-observed-effect concentration for bobwhite in the study was 1600 ppm, the highest level tested.

For the mallard duck there were no overt signs of toxicity or mortalities among adult birds exposed to dietary concentrations of 256, 600, or 1600 ppm Pyridate technical. No treatment related effects upon reproductive parameters were noted at 256, or 600 ppm concentrations. While not statistically significant, there appeared to be a slight reduction in hatchability at the 1600 ppm concentration. The no-observed-effect concentration for mallards in the study was greater than 640 but less than or equal to 1600 ppm.

0-24 72-1, Freshwater Fish LC50, Rainbow Trout and Bluegill:

The following 2 studies were submitted to the Agency on October 17, 1986:

1. ACUTE TOXICITY OF PYRIDATE TECHNICAL TO RAINBOW TROUT. J. Bowman, Study number 34819. Analytical Bio-Chemistry Laboratories, Inc., August 26, 1986. Results of the study indicated that the LC50 to trout was 1.2 ppm.

2. ACUTE TOXICITY OF PYRIDATE TECHNICAL TO BLUEGILL SUNFISH, J. Bowman, Study number 34303, Analytical Bio-Chemistry Laboratories, Inc., August 26, 1986. Results of the study indicated that the LC50 to bluegill was 2.1 ppm.

The studies were assigned accession numbers 265681 and 265682 and reviewed by the Agency on January 5, 1987. They were accepted as fulfilling guideline requirements for warmwater and coldwater fish.

D-25 72-1, Acute LC50, Daphnia:

The following study was submitted to the Agency on 1/23/84:

ACUTE TOXICITY OF PYRIDATE TECHNICAL TO DAPHNIA MAGNA, Project 009178, RCC, July 6, 1982. The results of the study indicated that the LC50 estimation for a 48 hour exposure of daphnia magna to Pyridate technical is 1.08 ppm with a 95% confidence interval of 1.02 - 1.15 ppm. The LC20 and LC80 are estimated to be 0.81 and 1.45 ppm respectively.

The study was assigned accession number 72350, reviewed, and classified as supplemental on May 18, 1984.

With the submission of additional data, accession number 264614, the study was reviewed by Daniel Rieder on April 28, 1987 and upgraded from supplementary to core.

D-26 72-3, Acute LC50, Marine Fish:

The study was submitted to the Agency on November 29, 1984. It was assigned accession number 73281 and reviewed on April 18, 1985. The study was found not scientifically sound because the test vessels were agitated and not analyzed. The main concern was that if the compound was volatile it would be lost from the vessels upon agitation. A discussion with the Agency indicated that if it could be shown that the compound was not volatile the study could probably be salvaged.

A new study was conducted to show the volatility and solubility of Pyridate in sea water. The test vessels were of the same size as those used in the original test and were agitated in the same manner. The solubility of Pyridate in sea water is approximately 0.3 ppm at 20 degrees C. The solutions never reached constant equilibrium because of two competing factors: 1) adsorption of the Pyridate to the glass walls of the containers, and 2) hydrolysis of the Pyridate to CL-9673. However, the material balance of greater than 96% clearly indicates no volatilization of Pyridate. It is also clear that at an attempted target of 1000

ppm, the highest test concentration, the fish were exposed to a saturated solution of Pyridate. There were no fatalities at any of the test concentrations, including 1000 ppm. A copy of the study, SOLUBILITY AND VOLATILITY STUDY OF 14C-PYRIDATE IN SEA WATER, Project 8712, A. Zohner Chemie Linz, October 1, 1987, is enclosed with this submission.

0-27 72-3, Acute LD<sub>50</sub> Embryo-larvae:

Study submitted 8/14/87. Received by the agency and assigned MRID No. 40303801. Study currently under review.

0-28 72-3, Acute LC<sub>50</sub> Marine shrimp:

Study submitted 11/27/84. Assigned accession number 73281. Approved by the agency 4/29/85. LC<sub>50</sub> = 40ppm (3.5-5.1% mortality) moderately toxic to marine shrimp.

0-29 141-01, Acute contact honey bee:

The LD<sub>50</sub> honey bee study was submitted to the agency 10/9/86. Additional copies were requested 10/1/87. The study was resubmitted to the Agency 10/8/87. The agency acknowledged receipt of the second submission and assigned MRID No. 40373202. The study is currently in scientific review.

0-30 171-2, Chemical Identity:

Please see 61-1 and 61-3, Product Chemistry.

0-31 171-3, Directions for use:

A label was submitted in the original data package of 1/25/85, Accession number 73306. However, new updated labels are submitted with this application.

0-32 171-4, Nature of residue, plants:

Plant metabolism studies were submitted in support of the ELIP registration for this product on 1/23/84, accession number 72351; and on 1/17/85, accession number 73282. However, three new metabolism studies:

- 1.) Metabolism of Pyridate and CL 9673 in broccoli.
- 2.) Metabolism of Pyridate and CL-9673 in peanuts.

3.) Metabolism of Pyridate and CL-9673 in corn.

are complete and final reports will be submitted to the Agency the week of January 11, 1988. The results of those studies confirm that the compounds of toxicological concern are Pyridate and its hydrolysis product CL-9673.

0-33 171-4, Residue Analytical Method:

In the original data submission of 1/23/84, four analytical methods were provided. The data was assigned accession number 72351, and accepted in Garbus' review of 10/7/85.

A simplified analytical method was provided to the Agency on 10/12/87 and assigned MRID number 40374801. The method is currently under review.

0-34 171-4, Magnitude of residues, crops:

January 25, 1985 Submission, Accession Number 73309

An uptake and decline study on peanuts was carried out at 3.6 lbs. active ingredient/acre. No residues were found at harvest. The half life was calculated to be 1.7 days. Recoveries were, 89% +/- 13.

Five (5) PAC studies using Tough™ 3.75EC and two (2) with Tough™ 45WP, were conducted on peanuts at 3.6 lbs. active ingredient/acre. No residues were found in nut meat. Recoveries were, 67 +/- 4%. No hay or hull samples were analyzed.

November 12, 1985 Submission, Accession Number 260814

Four residue studies were submitted on peanut hay and hulls not included in submission of January 25, 1985. There were no residues in the hulls and hay.

Report 823 Addendum 1, no residue in any of the hull samples, recovery rates 73 +/- 7%.

Report 823 Addendum 2, no residue in any hay sample recovery rates 71 +/- 6%.

Report 823 A. Plains, GA peanut trial analysis of nut meat. Samples taken 123 days after application. No residues were found in any of the samples. Recoveries: 68 +/- 9%.

Report 823 A, Addenda 1 & 2. Recovery rates 71 +/- 6% hulls, 73 +/- 7% hay. No residues were found in any of the hull or hay samples.

NOTE: A total of 6 peanut RAC trials plus one uptake and decline trial were conducted. The 6 RAC studies covered all major peanut growing areas of the U.S. Results showed no residues (>0.03ppm) in peanut nut meat, hulls, or hay.

0-35 171-6, Proposed tolerance:

A tolerance proposal is included with this submission. It proposes a tolerance of 0.03ppm on all RAC's and feed. This is being proposed because there are no detectable residues in any RAC's above the level of detection for the latest analytical method, which is 0.03ppm.

0-36 171-7, Reasonable grounds for support:

Reasonable grounds for support are contained in the enclosed study: PYRIDATE BENEFITS, John W. Kennedy Consultants, Inc., December 30, 1987.

0-37 171-13, Analytical standards:

Unlabeled PAI has been submitted to EPA Labs, Beltsville, and EPA Depository, RTF. Samples of radio labeled analytical grade standards will be provided upon request.

0-38 161-1, Hydrolysis:

The original submission was made to the Agency on 1/23/84. The study, DETERMINATION OF THE HYDROLYSIS OF PYRIDATE CL 11.3441 IN WATER AS A FUNCTION OF PH, A Zohner, et al, Report No 735, September 1981, was assigned accession number 72352 and reviewed on 5/21/84. The study was accepted as satisfying the data requirement.

0-39 161-2, Photodegradation Water:

The original study was submitted to the Agency on 1/23/84 and assigned accession number 72352. In there letter of 10/1/87 the Agency requested additional copies of the study which were submitted by the registrant on 10/08/87. MRID number 40377212 was assigned and the study is currently under review.

0-40 161-3, Photodegradation Soil:

The original study was submitted 11/29/84. It was assigned accession number 73283 and reviewed by the Agency 1/30/86. Deficiencies were determined to exist and were listed. All deficiencies are addressed in a report that will be available the first week in January, 1988.

0-41 162-1 Aerobic Soil Metabolism:

The original study was submitted 1/23/84. It was assigned accession number 72352 and found to contain deficiencies in the Agency's review of 5/10/84. It was replaced by a new study, AEROBIC SOIL METABOLISM STUDY OF 14C-CL9673, THE MAIN METABOLITE OF 14C-PYRIDATE, IN SOIL, Report No 832, submitted 2/25/86. Accession no 261827 was assigned and the new study was accepted by the Agency as fulfilling the aerobic soil metabolism requirement.

0-42 162-2, Anaerobic Soil Metabolism:

A new study ANAEROBIC SOIL METABOLISM STUDY OF 14C-CL9673, THE HYDROLYZATION PRODUCT OF 14C-PYRIDATE, has been completed and is a part of this submission.

0-43 163-1, Leaching and Adsorption/Desorption:

Gilmore submitted four studies to the Agency on 2/25/86. Accession number 261827 was assigned to the data and it was reviewed by the Agency on 5/13/86. The studies were accepted, but additional data was requested. After an extensive review of existing and new data, the registrant believes sufficient data has been submitted to satisfy this requirement. A request to the Agency to reconsider the data has been prepared and is a part of this submission.

0-44 164-1, Soil Dissipation, Field:

Four soil dissipation studies conducted in different geographic areas of the country have been completed. The final reports have been completed and are part of this submission.

0-45 165-1, Confined Rotational Crops:

The original data submission, submitted 1/23/84, was assigned accession number 72352 and reviewed by the Agency 5/21/84. The study was rejected because it was conducted in foreign soil. A

second study, CONFINED ACCUMULATION STUDIES ON ROTATIONAL CROPS WITH 14C-PYRIDATE, July 1985, A Zohner, was assigned accession number 264980 and reviewed by the Agency on 12/24/86. It was also rejected.

A request to have the Agency reconsider the data is a part of this submission. The registrant feels the data contains sufficient information to satisfy the Agency's concerns.

0-46 165-2, Rotational Crops, Field:

Based on the confined rotational crop data the registrant feels that there is no need for field rotational data. A request to the Agency to waive this requirement has been prepared and is a part of this submission.

0-47 165-4, Accumulation in Fish:

The original study was submitted 1/17/85, and assigned accession number 73283. It was accepted by the Agency as satisfying the requirement on 2/11/86. Please note, a BCF of 464 in whole fish was referenced in Mr. R. Taylor's letter of approval of 2/11/86. However, this is an error as the study author indicated a BCF in whole fish of 116.

DATA REQUIREMENT LISTING FOR THE ACTIVE METHOD OF REPORT

1. PRODUCT NAME: TOUGH 3.75EC	2. EPA REG.NO/FILE SYMBOL 42545-	3. FORMULATOR'S EXEMPTION SELECTED YES _____ NO <input checked="" type="checkbox"/> X	4. PAGE 1 of 1
5. APPLICANT'S NAME AND ADDRESS GILMORE, INC. 1755 N. Kirby Parkway, Suite 300 Memphis, TN 38119	6. APPLICATION FOR REGISTRATION DATED 12 /31 /87 Mo. Day Yr.	7. NAME OF ACTIVE INGREDIENT(S): Pyridate	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER					
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter(P) or Certifi- cation (OTP) Indi- cate "P" or "OTP"	9e. Public Litera- ture	9f. N.A. or Waiver or other (Explain)						
158.20	PRODUCT CHEMISTRY												
61-1	Identity of ingredients	X	1/25/85				0-1	0	7	3	3	0	6
61-2	Statement of composition		1/25/85				0-1	0	7	3	3	0	6
61-3	Discussion of formation of impurities		1/23/84				0-2	0	7	2	3	5	3
62-1	Preliminary analysis		1/25/85					0	7	3	3	0	6
62-2	Certification of limits		1/25/85					0	7	3	3	0	6
62-3	Analytical methods for enforcement limits		1/23/84				0-3	0	7	2	3	5	3
63-2	Color		1/23/84 1/25/85					0	7	2	3	5	3 0
63-3	Physical state		1/23/84 1/25/85					0	7	2	3	5	3 0
63-4	Odor		1/23/84 1/25/85					0	7	2	3	5	3 0
63-5	Melting point		1/23/84					0	7	2	3	5	3
63-6	Boiling point		1/23/84					0	7	2	3	5	3
63-7	Density, bulk-density, or specific gravity		1/23/84 1/25/85					0	7	2	3	5	3 0

DATA REQUIREMENT LISTING FOR THE ACTIVE METHOD C REPORT

1. PRODUCT NAME: TOLIGH 3.75EC	2. EPA REG.NO/FILE SYMBOL 42545-	3. FORMULATOR'S EXEMPTION SELECTED YES _____ NO <input checked="" type="checkbox"/> X	4. PAGE <u>2</u> of <u>9</u>
5. APPLICANT'S NAME AND ADDRESS GILMORE, INC. 1755 N. Kirby Parkway, Suite 300 Memphis, TN 38119	6. APPLICATION FOR REGISTRATION DATED <u>12 /31 / 87</u> Mo. Day Yr.	7. NAME OF ACTIVE INGREDIENT(S): Pyridate	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER	
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter(P) or Certifi- cation (OTP) Indi- cate "P" or "OTP"	9e. Public Litera- ture	9f. N.A. or Waiver or other (Explain)		
158.20	PRODUCT CHEMISTRY (Continued)								
63-8	Solubility	X	1/23/84					0	7 2 3 5 3
63-9	Vapor pressure	X	1/23/84					0	7 2 3 5 3
63-10	Dissociation constant	X	1/23/84					0	7 2 3 5 3
63-11	Octanol/water partition coefficient	X	1/23/84					0	7 2 3 5 3
63-12	pH	X	1/23/84				NA-1	0	7 2 3 5 3
63-13	Stability	X	1/23/84					0	7 2 3 5 3
63-14	Oxidizing/reducing reaction	X	1/25/85					0	7 3 3 0 6
63-15	Flammability	X	1/25/85					0	7 3 3 0 6
63-16	Explodability	X	1/25/85					0	7 3 3 0 6
63-17	Storage stability	X	1/25/85					0	7 3 3 0 6
63-18	Viscosity	X	1/25/85					0	7 3 3 0 6
63-19	Miscibility	X	1/25/85					0	7 3 3 0 6

DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD C IMPORT

1. PRODUCT NAME: TOUGH 3.75 EC	2. EPA REG.NO/FILE SYMBOL <u>41545-</u>	3. FORMULATOR'S EXEMPTION SELECTED YES _____ NO <u>X</u>	4. PAGE <u>3</u> OF <u>9</u>
5. APPLICANT'S NAME AND ADDRESS GILMORE, INC. 1755 N. Kirby Parkway, Suite 300 Memphis, TN 38119	6. APPLICATION FOR REGISTRATION DATED <u>12 /31 /87</u> Mo. Day Yr.	7. NAME OF ACTIVE INGREDIENT(S): PYRIDATE	

## DATA REQUIREMENT LISTING FOR THE ACTIVE METHOD OF REPORT

1. PRODUCT NAME: TOUGH 3.75 EC	2. EPA REG.NO/FILE SYMBOL 41545-	3. FORMULATOR'S EXEMPTION SELECTED YES _____ NO <input checked="" type="checkbox"/> X	4. PAGE <u>4</u> OF <u>9</u>
5. APPLICANT'S NAME AND ADDRESS GILMORE, INC. 1755 N. Kirby Parkway, Suite 300 Memphis, TN 38119	6. APPLICATION FOR REGISTRATION DATED 12 / 31 / 87 Mo. Day Yr.	7. NAME OF ACTIVE INGREDIENT(S): PYRIDATE	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER						
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter(P) or Certifi- cation (OTP) Indi- cate "P" or "OTP"	9e. Public Litera- ture	9f. N.A. or Waiver or other (Explain)		0	7	3	2	8	0
158.135	TOXICOLOGY							0-4	0	7	3	2	8	0
81-1	Acute oral LD-50, rat	X	1/17/85 1/25/85						0	7	3	3	0	7
81-2	Acute dermal LD-50	X	1/17/85 1/25/85					0-5	0	7	3	3	0	7
81-3	Acute inhalation LC-50, rat	X	1/23/84 1/25/85					0-6	0	7	3	2	8	0
81-4	Primary eye irritation, rabbit	X	1/25/85					0-7	0	7	3	3	0	7
81-5	Primary dermal irritation	X	1/25/85					0-8	0	7	3	3	0	7
81-6	Dermal sensitization	X	1/23/84					0-9	0	7	2	3	8	0
82-1	90-day feeding, rat	X	4/06/87					0-10	4	0	1	5	7	4
82-1	90-day feeding, dog	X	2/27/87					0-11	4	0	1	0	1	6
83-1	Chronic feeding, rat	X	1/23/84					0-12	0	7	2	3	4	2
83-1	Chronic feeding, dog	X	1/23/84					0-13	0	7	2	3	4	4
83-2	Oncogenicity, rat	X	1/23/84					0-14	0	7	2	3	4	3
83-2	Oncogenicity, mouse	X	1/23/84					0-15	0	7	2	3	4	6

**DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD OF REPORTING**

1. PRODUCT NAME: TOUGH 3.75EC 5.	2. EPA REG.NO/FILE SYMBOL 42545-	3. FORMULATOR'S EXEMPTION SELECTED YES _____ NO <input checked="" type="checkbox"/> X	4. PAGE <u>5</u> OF <u>9</u>
APPLICANT'S NAME AND ADDRESS GILMORE, INC. 1755 N. Kirby Parkway, Suite 300 Memphis, TN 38119	6. APPLICATION FOR REGISTRATION DATED <u>12/31 / 87</u> Mo. Day Yr. .	7. NAME OF ACTIVE INGREDIENT(S): PYRIDATE	

DATA REQUIREMENT LIST FOR THE ACTIVE METHOD OF REPORT

1. PRODUCT NAME: TOUGH 3.75EC	2. EPA REG.NO/FILE SYMBOL 42545-	3. FORMULATOR'S EXEMPTION SELECTED YES _____ NO <u>X</u>	4. PAGE <u>6</u> of <u>9</u>
5. APPLICANT'S NAME AND ADDRESS GILMORE, INC. 1755 N. Kirby Parkway, Suite 300 Memphis, TN 38119	6. APPLICATION FOR REGISTRATION DATED <u>12 / 31 / 87</u> Mo. Day Yr.	7. NAME OF ACTIVE INGREDIENT(S): Pyridate	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER									
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter(P) or Certifi- cation (OTP) Indi- cate "P" or "OTP"	9e. Public Litera- ture	9f. N.A. or Waiver or other (Explain)										
158.145	WILDLIFE & AQUATIC REQUIREMENTS							0-21	4	0	3	7	3	2	0	1	
71-1	Avian oral LD-50, bobwhite	X	10/08/87					0-22				7	2	3	5	0	
71-2	Avian dietary LC-50, bobwhite	X	1/23/84					0-22				7	2	3	5	0	
71-2	Avian dietary LC-50, mallard	X	1/23/84					0-23				7	2	3	5	0	
71-4	Avian reproduction, bobwhite																
71-4	Avian reproduction, mallard							0-23									
72-1	Freshwater fish, bluegill	X	10/17/86					0-24				2	6	5	6	8	2
72-1	Freshwater fish, trout	X	10/17/86					0-24				2	6	5	6	8	1
72-2	Acute LC-50, daphnia	X	1/23/84					0-25				7	2	3	5	0	
72-3	Acute LC-50, marine fish	X	11/29/84					0-26				7	3	2	8	1	
72-3	Acute LC-50, embryo-larvae	X	8/14/87					0-27	4	0	3	0	3	8	0	1	
72-3	Acute LC-50, marine shrimp	X	11/29/84					0-28				7	3	2	8	1	

DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD C SUPPORT

1. PRODUCT NAME: TOUGH 3.75EC	2. EPA REG.NO/FILE SYMBOL <u>42545-</u>	3. FORMULATOR'S EXEMPTION SELECTED YES <u>      </u> NO <u>  X  </u>	4. PAGE <u>  7  </u> OF <u>  9  </u>
5. APPLICANT'S NAME AND ADDRESS GILMORE, INC. 1755 N. Kirby Parkway, Suite 300 Memphis, TN 38119	6. APPLICATION FOR REGISTRATION DATED <u>12 / 31/ 87</u> <u>Mo. Day Yr.</u>	7. NAME OF ACTIVE INGREDIENT(S): PYRIDATE	

## DATA REQUIREMENT LIST FOR THE ACTIVE METHOD OF REPORT

1. PRODUCT NAME: TOUGH 3.75EC	2. EPA REG.NO/FILE SYMBOL 42545-	3. FORMULATOR'S EXEMPTION SELECTED YES _____ NO <input checked="" type="checkbox"/> X	4. PAGE <u>8</u> of <u>9</u>
5. APPLICANT'S NAME AND ADDRESS GILMORE, INC. 1755 N. Kirby Parkway, Suite 300 Memphis, TN 38119	6. APPLICATION FOR REGISTRATION DATED <u>12 / 31 / 87</u> Mo. Day Yr.	7. NAME OF ACTIVE INGREDIENT(S): PYRIDATE	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER			
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter(P) or Certifi- cation (OTP) Indi- cate "P" or "OTP"	9e. Public Litera- ture	9f. N.A. or Waiver or other (Explain)				
158.125	RESIDUE CHEMISTRY							0-30	7	3	3
171-2	Chemical identity	X	1/25/85					0-30	3	0	6
171-3	Directions for use	X	1/25/85					0-31	7	3	0
171-4	Nature of residue plants	X	1/23/84 1/17/85					0-32	7	2	3
171-4	Residue analytical method	X	1/23/84					0-33	7	2	3
171-4	Magnitude of residues, crops	X						0-34	7	3	0
171-4	Residues in processed food/feed							NA-3			
171-4	Residues in meat/milk/poultry/eggs							NA-4			
171-5	Reduction of residues							NA-5			
171-6	Proposed tolerance							0-35			
171-7	Reasonable grounds for support	X	12/30/87					0-36			
171-13	Analytical standards							0-37			

## DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD C SUPPORT

1. PRODUCT NAME: TOUGH 3.75EC		2. EPA REG.NO/FILE SYMBOL 42545-		3. FORMULATOR'S EXEMPTION SELECTED YES _____ NO X		4. PAGE 9 of 9						
5. APPLICANT'S NAME AND ADDRESS GILMORE, INC. 1755 N. Kirby Parkway, Suite 300 Memphis, TN 38119		6. APPLICATION FOR REGISTRATION DATED 12 /31 /87 Mo. Day Yr.		7. NAME OF ACTIVE INGREDIENT(S): PYRIDATE								
8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER				
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter(P) or Certifi- cation (OTP) Indi- cate "P" or "OTP"	9e. Public Litera- ture	9f. N.A. or Waiver or other (Explain)					
158.130	ENVIRONMENTAL FATE											
161-1	Hydrolysis	X	1/23/84			0-38		7	2	3	5	2
161-2	Photodegradation, water	X	10/08/87			0-39	4	0	3	7	3	2
161-3	Photodegradation, soil	X	11/29/84			0-40		7	3	2	8	2
162-1	Aerobic soil metabolism	X	2/25/86			0-41		2	6	1	8	2
162-2	Anaerobic soil metabolism	X	12/30/87			0-42						
163-1	Leaching adorption, desorption	X	2/25/86			0-43		2	6	1	8	2
164-1	Soil dissipation, field	X	12/30/87			0-44						
165-1	Confined rotational crops	X	9/19/86			0-45		2	6	4	9	8
165-2	Field rotational crops					0-46						
165-4	Accumulation in fish	X	1/17/85			0-47		7	3	2	8	3

TOUGH® 3.75 EC  
CFR 40 SECTION 158 DATA REQUIREMENTS  
COMMENTS IN SUPPORT OF "NOT APPLICABLE" POSITION

NA-1 63-12, pH:

The product is insoluble in water. Therefore, a pH determination is not required.

NA-2 63-21, DIELECTRIC BREAKDOWN VOLTAGE:

This product is not intended for use around electrical equipment. Therefore, dielectric breakdown voltage data is not required.

NA-3 171-4, RESIDUES IN PROCESSED FOOD/FEED:

No residues will be found in crops treated with the product in the manner indicated on the label. Therefore, determination of residues in processed food/feed is not required.

NA-4 171-4, RESIDUES IN MEAT/MILK/POULTRY/EGGS:

No residues will be found in crops treated with the product in the manner indicated on the label. Therefore, livestock and/or poultry feeding studies are not indicated.

NA-5 171-5, REDUCTION OF RESIDUES:

No residues will be found in crops treated with the product in the manner indicated on the label. Therefore, reduction of residue determinations are not indicated.